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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/26/2003

Li Ding

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12/22/2008

BROWN RUDNICK LLP
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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

12/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/722,968	Applicant(s) DING ET AL.	
	Examiner JENNIFER MYONG M. KIM	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 1-25 and 43-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-42 and 46-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The amendment filed October 2, 2008 have been received and entered into the application.

Action Summary

The rejection of claims 26-42 under 35 U.S.C. 102(b) as being anticipated by Delrieu et al. is being maintained for the reasons stated in the previous Office Action.

The rejection of claim 42 under 35 U.S.C. 103(a) as being unpatentable over Delrieu et al. (US Patent No. 6319507) is being maintained for the reasons stated in the previous Office Action.

Applicant's amendment necessitated the additional rejection presented in this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26, 46 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to claim 26, the phrases "avoiding substantial absorption of other bead ingredients", "substantially impermeable to other bead ingredient" and "largely impermeable agent" lack literal support in the specification as originally filed.

With regard to claim 46 the phrase "non-porous and do not substantially adsorb oil" lack literal support in the specification as originally filed.

With regard to claim 47 the phrase "a single gas bubble" lack literal support in the specification as originally filed.

This is a New Matter Rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 46-48 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 26, the term "largely" (describing an impermeable agent) is a subjective term; therefore, it is not clear what would qualify as an agent that would be "largely" impermeable without a specific quantification of "largely" impermeability. The term "other" (describing bead ingredients), it is not clear what "other" bead ingredients are intended.

Claims 46 and 47 recite the limitation "the plurality of hollow particles" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 48 recites the limitation "the hollow particles" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 51 recites the limitation "the density control agent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

These claims would not be further examined since it is not clear what the limitations are intended.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 26-41, 49, 50 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Delrieu et al. evidenced by Robinson et al. (U.S. Patent No. 6,852,266 B2).

Delrieu et al. teach, in col. 4 lines 5-43:

“The invention, as claimed, is intended to provide a remedy for the problem of providing a delivery system for delivering labile and other actives to the skin, or other body surface, for topical application in a cosmetic or pharmaceutical formulation. It furthermore solves problems of delivering actives that may react undesirably with the delivery system itself, damaging the active or causing stability problems with the formulation.

Accordingly, the invention provides a protective cosmetic particulate gel delivery system for a topically applied active agent comprising discrete gel particles formed of:

- a) an agar gel; and
- b) a restraining polymer dispersed in the agar gel, the restraining polymer having sufficient molecular weight to prevent egress of the restraining polymer from the agar gel, having retention groups to bind the active agent to the restraining polymer for retention in the gel particles and being present in a proportion sufficient to deliver an effective amount of the active agent; wherein the gel particles are manually crushable on the skin to increase the surface area of the gel particle material and expose the restraining polymer to the skin or other body surface for release of the active agent.

Preferably, active agent molecules are bound to the restraining polymer retention groups and the restraining polymer has an average molecular weight of at least 100,000

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daltons. In a preferred embodiment, the active agent and the retention groups both comprise polar groups and are of opposite polarity whereby the active agent can bind ionically with the retention groups. A suitable restraining polymer is water-soluble and has a polysaccharide backbone substituted with strongly cationic quaternary ammonium groups which can act as retention groups for a range of active agents. The cationic ammonium groups are able to form stable ionic bonds with anionic actives which bonds can be broken to release the active upon topical application of the containing cosmetic composition.

Delrieu et al. teach, in col. 5 lines 4-29:

“The invention also provides a method of preparing agar gel particles comprising the steps of:

a) dissolving agar in water heated to an elevated temperature sufficient to dissolve the agar, in a proportion of agar to water effective to form a gel at lower temperatures; and
b) mechanically dispersing the agar solution in a cold hydrophobic liquid immiscible with the agar solution maintained at a temperature below the agar gelling point;
with the improvement that a water-soluble restraining polymer is included in the agar solution whereby the drops are formed into gel beads incorporating the restraining polymer.

Preferably, though not necessarily, the hot agar solution to an intermediate temperature above the gelling point of the agar solution prior to performing step b). In a preferred embodiment, which is simple and economic to practice, the agar-restraining polymer solution is mechanically dispersed in the cold hydrophobic liquid by using a

rotating agitator. Using this method, the gel bead size can be controlled by selecting the rotation speed of the agitator.

In an alternative embodiment, the agar-restraining polymer solution is mechanically dispersed in the cold hydrophobic liquid by injection through a hollow needle to form drops, the needle having an internal dimension selected to provide a desired gel bead size.”

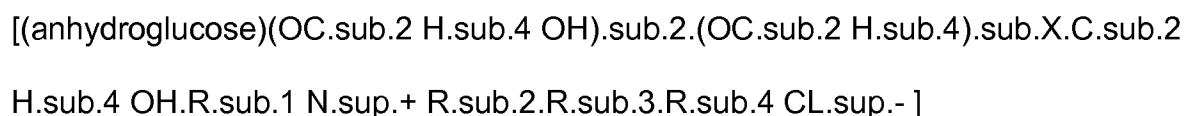
Delrieu et al. teach, in col. 8 line 64 to col. 9 line 60:

“Pursuant to the invention, it has been discovered that polymers with an average molecular weight of about 100,000 daltons, and more, are unable to flow through a preferred agar gel matrix. However, certain polymers, especially polymers capable of interacting with the agar, may be adequately retained in an agar gel, for the purposes of the invention even although they have a lower average molecular weight, e.g down to 75,000 daltons, or even as low as 50,000 daltons. There is no particular upper limit to the molecular weight of the restraining polymer, although it is contemplated that the average molecular weight will not exceed several million, e.g. 5 million daltons, but preferably does not exceed 1 million daltons. A preferred range for the average molecular weight is from 75,000 to 125,000 daltons.

Some preferred classes of restraining polymer are cationic polysaccharides and polypeptides or proteins. For example, some specific restraining polymers preferred for the practice of the invention are certain commercially available quaternized polysaccharides, especially celluloses, rich in quaternary groups, notably polyquaternium 24 available under the trademark QUATRISOFT LM-200 (Union

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Carbide Corporation), polyquaternium 11, available for example under the trade name GAFQUAT 755N (ISP Europe), and the CRODACEL Q (trademark) range of alkyl quaternary cellulose polymers (Croda, Inc.), notably laurdimonium hydroxyethylcellulose, sold under the trademark CRODACEL QL, cocodimonium hydroxyethylcellulose, sold under the trademark CRODACEL QM and steardimonium hydroxyethylcellulose, sold under the trademark CRODACEL QS. The CRODACEL Q (trademark) polymers belong to a class of polymers having repeating units of the following general nature:



where x is often unspecified but may be taken to be under 10 and may be 0; R.sub.1 is commonly methylene; R.sub.2 and R.sub.3 are frequently methyl and R.sub.4 is the characteristic longer alkyl group, e.g. 10-30 carbon atoms such as lauryl, cocoyl or stearyl. The polyquaternium 24 polymers lack the two hydroxyethyl substituents. Each anhydroglucose unit can have a maximum of three ethoxy substituents, as shown, but in practice, the average degree of ethoxy substitution will be substantially lower so that the indication of di-hydroxyethyl substitution should be regarded as a theoretical limit rather than a practical representation. Thus, each repeating anhydroglucose or saccharide unit contains up to two hydroxyethyl substituents and a quaternary ammonium group attached to the polysaccharide nucleus via a short polyethoxy chain. Polyquaternium polymers lack the longer alkyl group and the lipophilic character it confers.

Of particular importance is the quaternary nitrogen atom which provides a cationic binding site for anionic actives. The R.sub.4 alkyl chain can provide a lipophilic anchor for lipid or lipophilic actives. the CRODACEL Q (trademark) range of quaternized celluloses are more fully described in a product data sheet entitled "Crodacel Q range" from Croda Chemicals Ltd., UK, the disclosure of which is hereby incorporated herein by reference thereto. They are supplied as somewhat hazy or opaque viscous concentrates intended for dilution and are known as film-forming agents with particular application in hair shampoos and conditioners, where their ability to be substantive to the hair, i.e. to attach themselves to the hair in a substantive manner, without creating build-up, is valuable. These and similar polymers suitable for use in the practice of this invention are well known in the literature and are described, for example, in U.S. Pat. No. 5,135,748 (Ziegler et al.), U.S. Pat. No. 4,970,067 (Panandiker et al.), U.S. Pat. No. 5,288,484 (Tashjian) the disclosures of which are also hereby incorporated herein by reference thereto."

In col. 13 lines 24-30, Delrieu et al. disclose that the gel beads can be used in cosmetic compositions in concentrations of from 0.1-90 weight percent anticipating the "...method...wherein the gelling agent comprises about 1.5%...of claim 40.

In col. 14 lines 58-61, Delrieu et al. teach that the intermediate temperature is maintained at about 50°C. The office generally gives the term "about" a 10% range thus "about 50°C" is interpreted as 45-55°C.

In examples 1 and 2 the restraining polymer is present in the composition at a concentration of 1.5% by weight anticipating the "...method...wherein the restraining

polymer comprises about 0.2 to about 7.5%..." of claim 34. In example 5 the restraining polymer is present in a concentration of 7.5% by weight and the FD&C Blue colorant is present in a concentration of 0.5% by weight of the composition anticipating "...method...comprising pre-dispersing a pigment..." of claim 39.

In example 15, Delrieu et al. disclose the use of 1.6g of silica shells (density-control agent) with an apparent density of 0.5-1.0 g/in³, 1.5g agar (gel bead), 1.5 g PG-hydroxyethylcellulose stearyldimonium chloride (restraining polymer), 10g dipropylene glycol and 97 g water. Giving 1.3% of a density-control agent (see applicant's specification page 11, lines 10-20 detailing silica as a density controlling microsphere), 1.3% of a restraining polymer and 1.3% of the gel bead agar anticipating the "...method of preparing density-controlled beads..." of claim 26, the "...method...comprising..." of claim 27, the "...method...wherein the gel beads have an average particle diameter of from about 0.1mm to 10mm" of claim 28, the "...method...wherein the first temperature is about 90oC" of claim 29, the "...method...wherein a water-soluble restraining polymer is included..." of claim 30, the "...method...wherein the restraining polymer has a molecular weight of at least 50,000 daltons..." of claim 32, the "...method...wherein the gel particles are manually crushable..." of claim 33, the "...method...wherein the restraining polymer comprises about 0.2 to about 7.5%..." of claim 34, the "...method...wherein the intermediate temperature is about 45oC..." of claim 35, the "...method...wherein the density-control agent is pre-dispersed in oil..." of claim 36, the "...method...comprising admixing..." of claim 37, the "...method...wherein the density-control agent comprises heat-expandable microspheres..." of claim 38, the

“method...comprising pre-dispersing a pigment...” of claim 39, the “...method...wherein the gelling agent comprises about 1.5%...” of claim 40, the “...method...wherein the density-control agent comprises about 0.01% to about 5%...” of claim 41.

Delrieu teaches that the gelled product intended for incorporation into a cosmetics product, the method comprising adsorbing a gel-inhibiting solvent on **porous** silica particles, or the like and dispersing the solvent-laden particles in a gelling medium, the gelling medium comprising a solution or dispersion of a suitable gelling agent. (column 20, lines 1-10).

With respect to the density-reducing agent dispersed to give the particles a bulk density set forth in claims 49 and 50, since Delrieu teaches the same gelled bead product constitute with the same amount of the density-control agent set forth in claim 41, therefore, it would inherently provide the same density as set forth in claims 49 and 50.

Robinson et al. disclosed that the term “**porous**” is defined to mean certain “**hollows**”. (column 5, line 1). Robinson et al. is provided as an evidence to show that the claimed hollow particles set forth in claim 52 is well known in the art to interpret and encompassed by the term "porous" taught by Delrieu.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Delrieu et al. (US Patent No. 6319507).

Delrieu et al. is as set forth above.

Delrieu et al. does not teach density-control agents comprising about 0.02% to about 0.1%. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a variety of concentrations of a density-control agent as Delrieu et al. teach the use of a density-control agent and it is within the skill of one of ordinary skill in the art to adjust the concentration of density-control agents.

The examiner respectfully points out the following from MPEP 2144.05: “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Response to Arguments

Applicant's arguments filed December 7, 2007 have been fully considered but they are not persuasive. With regard to 35 U.S.C. 102(b) rejection, Applicant argues that Delrieu does not disclose or teach all of the elements of Applicant's invention because Delrieu has silica shell that absorb oil while the present innovation relates to a stable and uniform distribution of gel beads or other particulate material, dispersed in a liquid medium that can be obtained by including a density-reducing agent within the gel bead to provide the particle with a desired bulk density. Further, claims 26 and 27 recite the use of a substantially impermeable density-reducing agent. This is not found to be persuasive because the phrases "substantially impermeable" lack literal support in the specification as filed. Further, Applicants' limitation of "avoiding substantially absorption of **other** bead ingredients" do not specified that that oil is as "other".

Applicants argue that Delrieu et al does not use the density-control agent because on column 20, line 21, the shells are absorbent and thus do not provide effective control density. This is not found to be persuasive because it is noted that Applicants' density-reducing agent is substantially impermeable to "other" unspecified bead ingredients, however, it does not state that the other ingredient is "oil". Delrieu et al. teach the same bead material that encompasses all the physical limitation required by the instantly claimed invention. Therefore, it is expected that the bead material taught by Delrieu et al. would effectively control density as well. The arguments of counsel cannot take the place of evidence in the record. *In re Schulz*, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument

and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.”). Applicants argue that Delrieu et al. does not disclose nor teach the use of hollow particles to affect the density of the beads as required by the claims of Applicants’ disclosure. This is not found to be persuasive because Delrieu et al. teach that the porous inert particles or silica particles can be employed and that the term “porous” is well known in the art as “hallow” as evidenced by Robinson et al. (U.S. Patent No. 6,852,266 B2). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Applicants’ amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/

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Primary Examiner, Art Unit 1617

Jmk
December 12, 2008